by the year 2020, primarily because of external demands and internal investments.

PHP17

SURGICAL INNOVATION: DO WE NEED A MORE BALANCED FRAMEWORK FOR EVIDENCE?

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OBJECTIVES: Health technology assessment bodies are increasingly reviewing the clinical and economic evidence on various surgical procedures. Such reviews typically use a hierarchy of evidence, with randomized controlled trials (RCTs) designated Level I evidence and case-control and case-series studies designated Levels III and IV. The objective of this study was to explore the evidence available to determine the value of a well-established surgical procedure. **METHODS:** A structured search of PubMed was conducted on rotator cuff surgery using Medical Subject Heading search terms. Internet searches identified evidence-based guidelines for this condition. **RESULTS:** Two RCTs evaluating the efficacy of arthroscopic repair of rotator cuff tears concluded that arthroscopic repair was superior to the alternatives studied. Ten systematic reviews examining studies of surgical technique modifications for rotator cuff surgery were identified. All 10 reviews reported that, despite limitations, there was enough evidence to identify surgical techniques that resulted in improved clinical outcomes. Most of the systematic reviews found Level III or Level IV evidence for recommending one type of surgery over another. In 2010, the American Academy of Orthopaedic Surgeons (AAOS) published evidence-based guidelines to improve treatment for 25 different rotator cuff problems; 74 studies were deemed of sufficient quality for use in the guidelines. However, more than half of the 25 recommendations (n=15) were characterized as inconclusive owing to the levels of evidence available for review. **CONCLUSIONS:** The pharmaceutical framework for evidence hierarchy often may not be appropriate for surgical procedures and devices. There are challenges to running clinical trials in surgical setting, making them impractical and unaffordable. Especially with well-established procedures, evidence review will require a balanced approach using the best available evidence and clinical expertise.

PHP18

THE EVOLUTION OF OUTCOMES GUARANTEES, DO THEY ALIGN WITH THE PRINCIPLES OF THE AFFORDABLE CARE ACT (ACA)?

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OBJECTIVES: The Affordable Care Act (ACA) has been upheld by the United States Supreme Court. Four principles of the ACA are driving changes in the US health care system, those principles are improving outcomes, quality, safety and containing costs. This study looks at several product outcomes guarantees to see if they support the cited ACA principles to benefit the health care system. **METHODS:** A review and analysis of published payer coverage policies and contracts entered into by product manufacturers with several US payers. **RESULTS:** Three publically available examples were analyzed and described herein: a) WellPoint analyzed over 55,000 claims for use of zafirlukast, montelukast sodium and zileuton and determined that outcomes for these products were better and more cost effective even when used first-line, outside of FDA indication; b) Cigna entered into an agreement with Merck where additional rebates are paid by Merck if patients who are on sitagliptin if patients stay on therapy and see blood sugar levels fall; c) EMD Serono and Prime Therapeutics have an agreement where rebates are paid if the total cost of care of an interferon beta 1a patient is greater than a patient on other MS drugs, or if adherence to the drug exceeds a specified level. **CONCLUSIONS:** Outcomes guarantees by product manufacturers are still in their infancy in the United States, but recent examples show that payers are looking at these agreements as a way to improve outcomes and control costs. The ACA may help to drive more outcomes guarantee agreements because they do support the key principles of the ACA. Drug manufacturers must clearly understand how their products will perform when used outside of a clinical trial in order to negotiate such agreements.

PHP20

PAYER PERSPECTIVES ON THE FUTURE USE OF CER TO INFORM COVERAGE AND REIMBURSEMENT DECISIONS FOR NEW DRUGS

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OBJECTIVES: Our aim was to gather perspectives from a diverse group of payers on how the rapidly evolving field of comparative effectiveness research (CER)/relative effectiveness (RE) will impact evidentiary standards for pricing and coverage decisions by 2020. **METHODS:** We conducted semi-structured interviews with 16 senior officials representing large payers, accountable care organizations, HTA groups, and pricing and reimbursement bodies in the US and Europe. An online survey was used to assess current use of CER/RE evidence and potential trends that might influence its use for decision making by 2020. The interview was designed to elicit their definitions of CER/RE and structured around 4 hypothetical cases resembling therapeutics expected to be more common and poised to create policy challenges by 2020. Topics included acceptance of designs (e.g., pragmatic trials) and analytic methods associated with CER/RE (e.g., indirect comparisons). A systematic content review was used to extract relevant information. **RESULTS:** While there was marked diversity in responses, there were some common themes. Respondents anticipate growing reliance on policy levers such as conditional reimbursement and prior authorization to control diffusion. Randomization will remain an essential component to assess comparative effectiveness. Respondents anticipate more aggressively using techniques like cluster randomization to conduct studies in their population. Case studies provided important insights into situations when certain types of CER evidence may be acceptable (e.g., observational data when differences between drugs are largely convenience). Payers would like to see but remain skeptical about harmonized approaches such as adaptive licensing to stage evidence development. **CONCLUSIONS:** Industry perceptions that CER will change payers' evidentiary requirements in the future are consistent with our findings. This arises both from a growing investment in analyses of their own data and increased reliance on policy tools to control diffusion that will drive the type of evidence industry will be required to produce.

PHP21

A FRAMEWORK FOR CONSIDERING COMPARATOR(S) FOR REGULATORY AND HTA PURPOSES

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OBJECTIVES: In the development and post-launch support of medicines, there are a myriad of issues in selecting comparator(s) for trials, studies, modeling and/or other analyses. The principles and process for the selection of comparators has a limited body of literature focused mainly on the randomized control trial design. Guidance documents exist but are not always sufficiently clear or consistent in their criteria. Our objective is to examine the complexities in making a generalizable comparator selection considering the many issues and questions found in the literature. **METHODS:** We conducted a comprehensive search of the published and grey literature, guidelines from regulatory, HTA, and professional organizations that addressed the comparator selection process as well as case studies and published opinion on the issue. We excluded publications that did not address issues, principles, and criteria for selecting comparators. We independently assessed this review with the final framework developed by team consensus. **RESULTS:** We propose a framework organizing the principles, methods and unresolved issues for the appropriate selection of a comparator product. It consists of: 1) foundational elements (e.g., clinical equipoise, ethical issues); 2) gaps in existing knowledge (e.g., systematic evidence reviews, is there a clear standard of care?); 3) hypotheses/questions to be addressed (e.g., intended purpose of the study/analysis, known characteristics of the investigational product); 4) study or analyses design-specific comparator criteria; and 5) exploration and validation of the proposed choice(s). **CONCLUSIONS:** Currently, several efforts are underway to define a clear and equitable process for comparator selection that is more consistent and acceptable to decision-makers and stakeholders. Our proposed framework could help support development of a more transparent and harmonized comparator selection process that better addresses the evidence needs of industry, regulators, HTA agencies and payers.

PHP22

MEDICATION USE SURVEY OF INPATIENTS WITH BASIC MEDICAL INSURANCE FROM 2009 TO 2010

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OBJECTIVES: To understand hospitalization costs, expenses covered by insurance and disease distribution among urban inpatients with basic health insurance (BHI) in China between 2009 and 2010, providing data evidence for the government further improving BHI policies and drug regulation system. **METHODS:** A nationwide, cross-sectional sampling of urban inpatients with BHI was conducted in mainland China. A retrospective analysis was adopted and all results were extrapolated to the whole country according to the population, economics and other factors in the inpatients' cities. The statistics analysis software was SQL Server 2003. **RESULTS:** There were 31,460,000 cases after extrapolated (sample=236,366) in 2010, with an increase of 13.92% than that of the previous year. Second-class hospitals received more hospitalization cases (45.47% of the total) in 2010 than the previous year (41.28% of the total). Average hospitalization cost per visit in 2010 was 8056 RMB, an increase of 5.05% from the previous year. Remarkably, medication expenses accounted for about 49%, which was approximately equal to the previous year. The expenses covered by BHI accounted for 67.73% for each vist, which was higher than that of the previous year. Cerebrovascular disease had the most hospitalization cases (9.95% of the total), followed by cancer, ischemic heart disease, Hypertension and chronic lower respiratory diseases. The total hospitalization cost of cancer (36.403 billion RMB) was the highest, followed by cerebrovascular disease (25.242 billion RMB) and ischemic heart disease (20.472 billion RMB). **CONCLUSIONS:** The average hospitalization costs per visit and total hospitalization costs all increased. And rational drug use should be still paid more attention since the drug costs percentage was steadily high. Helping inpatients select proper hospitals to see doctors and strengthening the administration of diseases cost highly will be helpful for reducing the medical costs.

PHP23

THE 2012 PRICE TREND ANALYSIS FOR 12 LEADING THERAPY AREAS IN 12 SELECTED DEVELOPED ADN EMERGING MARKETS

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